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Dated: June 5, 2009 Signature: /Mark D. Russett/
Mark D. Russett, Reg. No. 41,281

Docket No.: 66585(70820)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent / Patent Application of:
Tsuneo Yasuma et al.

U.S. Patent No. 7,514,441

Issue Date: April 7, 2009

Application No.: 10/525,158

Confirmation No.: 5896

Filed: February 22, 2005

Art Unit: 1624

For: SUBSTITUTED PYRAZOLO[1,5-
A]PYRIMIDINES AS CALCIUM RECEPTOR
MODULATING AGENTS

Examiner: Moore, Susanna

**RENEWED REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT
UNDER 37 C.F.R. §1.705(b)/1.705(d)**

MS Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants are in receipt of the Decision dated February 12, 2009, holding in abeyance a decision on the "Request for Reconsideration of Patent Term Adjustment (PTA) under 37 C.F.R. § 1.705(b)" filed on October 28, 2008.

This is a Renewed Request for Reconsideration of Patent Term Adjustment (PTA) under 37 C.F.R. § 1.705(b) (or, alternatively, a Petition for Review of Patent Term Adjustment under 37 C.F.R. §§ 1.181 & 1.705(b)/1.705(d), if appropriate) to correct the Patent Term Adjustment for the above-referenced patent application.

It is respectfully submitted that the Patent Term Adjustment of five hundred forty-five (545) days accorded by the Patent Office to the above-referenced application in the "Determination of Patent Term Adjustment" mailed July 28, 2008, and the Patent Term Adjustment of five hundred eighty-three (583) days indicated on the issued patent, are

not correct, or at least are not complete. Applicants respectfully request the grant of a minimum Patent Term Adjustment of nine hundred fifty-five (955) days, as discussed herein.

STATEMENT OF FACTS

1. Applicants filed the instant application pursuant to 35 U.S.C. § 371(b) on February 22, 2005, as the U.S. national phase of PCT International Application No. PCT/US03/26317, filed August 21, 2003. The Notice of Acceptance mailed from the U.S. Patent and Trademark Office (the "Office") on October 14, 2005, acknowledged that the application fulfilled all the requirements of 35 U.S.C. § 371 on February 22, 2005.
2. The Office mailed a Restriction Requirement on October 19, 2007. This was the first action under 35 U.S.C. § 132 in the application.
3. As of February 22, 2008 (*i.e.*, three years after the date that the application fulfilled all the requirements of 35 U.S.C. § 371), a patent had not issued from this patent application.
4. During prosecution, there was no request for continued examination, no interference proceeding, no imposition of a secrecy order, and no review by the Board of Patent Appeals and Interferences or a Federal Court. The instant application/patent is not subject to a terminal disclaimer.
5. The Office mailed a Notice of Allowance on July 28, 2008, together with a "Determination of Patent Term Adjustment" indicating that the patent issuing on the present application would be entitled to five hundred forty-five (545) days of Patent Term Adjustment under 35 U.S.C. § 154(b) "[i]f the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday

before the date that is 28 weeks (six and a half months) after the mailing date of this notice”.

6. Applicants timely paid the issue fee on October 28, 2008. Applicants also filed a “Request for Reconsideration of Patent Term Adjustment” on October 28, 2008, stating that the application is entitled to additional PTA. Because the patent had not then issued, the total amount of PTA was not known at that time.

7. The Office issued a paper titled “On Application for Patent Term Adjustment” on February 12, 2009, holding in abeyance Applicants’ request for reconsideration of PTA (the “Decision”). A copy of the Decision is attached hereto as Exhibit A.

8. The application ultimately issued as U.S. Patent No. 7,514,441 on April 7, 2009. The Patent Term Adjustment indicated on the issued patent is five hundred eighty-three (583) days. The Office’s failure to issue the patent within four months of payment of the issue fee (i.e., by February 28, 2009) evidently resulted in an additional 38 days of PTA.

9. The patent issue date of April 7, 2009, is 410 days after February 22, 2008 (*i.e.*, three years after the date that the application fulfilled all the requirements of 35 U.S.C. § 371).

10. The Decision dated February 12, 2009, indicated that a request for reconsideration of the PTA should be filed within two months of the date of patent issuance. As noted above, the patent issued on April 7, 2009, and this paper is being filed within two months of the issue date (consistent with the Decision and 37 C.F.R. § 1.705(d)), so this paper is timely filed.

11. It is believed that no fee is due in connection with the filing of this paper (as acknowledged in the Decision).

**APPLICANTS ARE ENTITLED TO ADDITIONAL PATENT TERM ADJUSTMENT
UNDER 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b)**

12. An inspection of the Patent Term Adjustments page on PAIR, a copy of which is attached hereto as Exhibit B, reveals that the Office accorded, as of July 28, 2008 (the mailing date of the Notice of Allowance and Fee(s) due), five hundred forty-five (545) days of Patent Term Adjustment attributable to USPTO delay under 35 U.S.C. § 154(b)(1)(A). This is consistent with the delay between April 22, 2006 (14 months from the date the present application fulfilled all requirements of 35 U.S.C. § 371) and October 19, 2007 (the date of mailing of an action under 35 U.S.C. § 132), pursuant to 35 U.S.C. § 154(b)(1)(A)(i) and 37 C.F.R. § 1.702(a)(1). Subsequently, the Office also accorded an additional 38 days of PTA attributable to USPTO delay under 35 U.S.C. § 154(b)(1)(A)(iv) due to the Office failure to issue the patent within four months of payment of the issue fee (i.e., by February 28, 2009). Thus, the total determination of PTA under 35 U.S.C. § 154(b)(1)(A) is five hundred eighty-three (583) days.

13. A further inspection of the Patent Term Adjustments page on PAIR (Exhibit A), reveals that the Office did not accord any days of Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) ("the Three Year Rule"). As noted above, the patent issued on April 7, 2009, which is 410 days after February 22, 2008 (i.e., three years after the date that the application fulfilled all the requirements of 35 U.S.C. § 371). The patent should therefore be accorded 410 days of PTA pursuant to the Three Year Rule. Because the Office did not accord any days of Patent Term Adjustment under the Three Year Rule, it appears that the Office has incorrectly applied the "double-counting" provision of 35 U.S.C. § 154(b)(2)(A).

14. 35 U.S.C. § 154(b)(2)(A) provides:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

15. In a Memorandum Opinion issued on September 30, 2008 in Wyeth v. Dudas, the U.S. District Court for the District of Columbia held that Office's interpretation of § 154(b)(2)(A), as published at 69 Fed. Reg. 34238 and (apparently or potentially) applied to the present patent application/patent, is incorrect. Wyeth v. Dudas, 580 F. Supp. 2d 138, 88 U.S.P.Q.2d 1538 (D.D.C. 2008), appeal docketed No. 08-5502 (Fed. Cir. Dec. 24, 2008).

16. The Wyeth court held that "[t]he only way that periods of time can 'overlap' is if they occur on the same day." Id. Accordingly if a delay under § 154(b)(1)(A) occurs on one calendar day, and a delay under § 154(b)(1)(B) occurs on another day, "they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day." Id.

17. Applicants respectfully submit that the five hundred eighty-three (583) days of delay under § 154(b)(1)(A) does not overlap with the 410 days of delay under § 154(b)(1)(B), except for the 38 days of PTA attributable to USPTO delay under 35 U.S.C. § 154(b)(1)(A)(iv) (failure to issue the patent within four months of payment of the issue fee). The non-overlapping nature of the § 154(b)(1)(A) and § 154(b)(1)(B) delays in this application (except as noted above) is illustrated below as Figure 1.

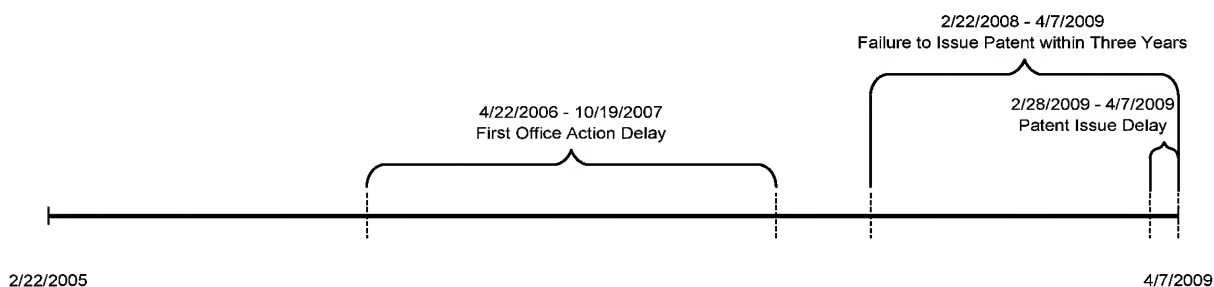


Figure 1

18. The patent is therefore entitled to PTA of five hundred eighty-three (583) days of delay under § 154(b)(1)(A), plus four hundred ten (410) days of delay under § 154(b)(1)(B), less the 38 days of overlap, for a total PTA of nine hundred fifty-five (955) days.

RELIEF REQUESTED

19. Applicants respectfully request that the Office (i) properly calculate the Patent Term Adjustment under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b) to which the present application/patent is entitled, and (ii) grant Patent Term Adjustment of at least nine hundred fifty-five (955) days (the sum of the delays under § 154(b)(1)(A) (545 days) and § 154(b)(1)(B) (410 days), excluding the 38 days of overlap), as set forth above.

20. Applicants believe that there are no fees due in connection with this renewed Petition. However, if additional fees are due, the Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 04-1105 under Order No. 66585(70820).

Dated: June 5, 2009

Respectfully submitted,

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